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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,094	10/06/2000	Bernhard H. Weigl	5SMV33.1	1122

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EXAMINER
HANDY, DWAYNE K

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 10/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/684,094	Weigl et al.
Examiner	**Art Unit**
Dwayne K. Handy	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 5, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *3, 4, 6-14, and 16* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☒ Claim(s) *3, 4, 6-14, and 16* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner previously rejected claim 16 due to the unclear location of the orifices. This has been corrected by amendment and this reason for the rejection is lifted. In both the original and amended claim 16, however, applicant recites the limitation of the orifices providing a "higher static resistance than a single orifice but a substantially lower dynamic resistance to flow". The use of the relative terms "higher" and "lower" renders the claim indefinite as well. Even given the fact the fact that the Examiner understands that the term high is used to qualify over the static resistance of a single orifice, the phrase which includes the term higher is still indefinite since it is unclear as to how much resistance is provided by the single orifice to begin with. As to the phrase "lower dynamic resistance to flow", the Examiner asks, lower than what? How much dynamic resistance is required to meet the limitation of low enough to control the flow? Since the Examiner overlooked this rejection in making his initial rejection, this would be considered a new grounds of rejection and as such, the Examiner has not made this action Final.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

4. Claim 16 was previously rejected under 35 U.S.C. 102(e) as being anticipated by Kellogg et al. (6,143,248). This rejection has been removed in light of applicant's amending of the claim in papers submitted 8/9/02.

Inventorship

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-4 were previously rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al. (5,856,174) in view of Parsons et al. (5,248,479). Claims 1 and 2 have been canceled, therefore the rejection of those claims is moot. Claims 3 and 4 remain in amended form and the Examiner feels the rejection still applies to these claims even in their amended form. Therefore, the rejection of these claims over Lipshutz and Parsons remains. Please see

Response to Arguments for a further discussion. The previous rejection is repeated below for applicant's convenience.

Lipshutz et al. recites a microfluidic device which contains channels and reservoirs for manipulating fluids for the purpose of performing analysis on the fluids in the channels and reservoirs (column 4, lines 4-45). The reference recites that the device may be used to filter materials (column 30, lines 15-28). "The filters may generally be within the apparatus, e.g., within the fluid passages leading from the sample preparation/extraction chamber. Lipshutz does not teach absorbent use as the driving means in a channel. Parsons et al. teach an agglutination reaction device (Figs 1-which uses a porous absorbent member (4) to draw fluid through a channel. Parsons also shows a triangular shaped area (7) which is also used to help draw fluid through the device. It would have been obvious to one of ordinary skill in the art to combine the teaching of absorbent fluid driving means in a channel with the device of Lipshutz. Lipshutz already teaches that absorbent may be used for filtration and that it may be in passages leading to and from chambers of the device. It would be obvious to use this absorbent as fluid driving means as taught by Parsons as well. This would allow for fluid control without external means providing the control.

9. Claims 5-12 were previously rejected under 35 U.S.C. 103(a) as being unpatentable over Yager et al. (5,716,852) in view of Lipshutz et al. (5,948,684). Claim 5 has been canceled, but

claims 6-12, even though amended, remain rejected over Yager in view of Lipshutz. Applicant has amended claim 6 to now include a vent. This feature is recited in Lipshutz in column 17, lines 28-60. Amended claim 7 recites a second stream. The Examiner believes this does not distinguish the instant claims over the previously made rejection either. Please see Response to Arguments below. The previous rejection made by the Examiner is repeated below for applicant's convenience.

Yager et al. (5,716,852). Yager et al. teach a microfabricated diffusion based sensor. The sensor is described best in column 3, lines 18-37 and includes a channel cell system in a substrate comprising a laminar flow channel, at least two inlet means in fluid connection with said laminar flow channel for respectively conducting into said laminar flow channel (1) an indicator stream...and (2) a sample stream. The laminar flow channel has depth sufficient enough to allow laminar flow of the streams adjacent to one another. The channel cell system may also include optical detection equipment for determining fluid properties in the laminar channel. Two embodiments of the channels of the device are shown in Figures 1 and 3 and described in columns 7-8. In describing operation of the device in column 7, Yager states that "...the sample containing small molecules of interest, sample stream 80, is brought into the device through sample stream inlet port (30), from whence it flows into sample stream channel (50), where it is referred to sample inlet stream (55). An indicator stream 70 is brought into indicator stream inlet port (20), from whence it flows into indicator stream inlet channel (40), where it is referred to as

indicator inlet stream (45). Sample inlet stream (55) meets indicator inlet stream (45) at T-joint 58 at the beginning of flow channel 100, and the two streams flow in parallel laminar flow as indicator stream (70) and sample stream (80) to exit port (60)...Due to the low Reynolds number in the small flow channel 100, no turbulence-induced mixing occurs and the two streams flow parallel to each other without mixing." The fact that the sample and indicator streams meet in the channel in parallel laminar flow means the fluid must have been in laminar flow upon exiting the entrance passageways (claims 5 and 6 recite a "smooth constant stream" or "smooth, continuous stream"). Also, Yager recites a plurality of viewing windows (140) for examining the contents of the flow channel. Yager et al. does not teach reservoirs in the surface of the device which contains the channels. Instead, Yager teaches input and output ports as well as injections for adding fluid to the device to be tested.

Lipshutz also teaches a microfluidic device for fluid assays. The device contains a microfluidic network for manipulation of fluids which has channels and reservoirs. For example, Lipshutz recites the use of chambers as storage reservoirs in column 19, lines 30-40. Specifically, Lipshutz recites element #412 as a waste reservoir. It would have been obvious to one of ordinary skill in the art to combine the reservoir teaching of Lipshutz with the device of Yager. Providing reservoirs for reagent addition as well as for waste collection at the end of an analysis channel would remove the need for additional equipment to load and/or remove fluids from the testing device. In fact, the device could be provided as a self-contained diagnostic device which comes with reagents already loaded.

10. Claims 13 and 14 were previously are rejected under 35 U.S.C. 103(a) as being unpatentable over Yager et al. and Lipshutz et al. and further in view of Kellogg et al. (6,143,248). This rejection remains as applicant's arguments have been directed to the references Yager and Lipshutz. As previously stated, the Examiner disagrees with those arguments.

Response to Arguments

11. Applicant's arguments filed 8/5/02 have been fully considered but they are not persuasive.

In reference to claims 3 and 4, applicant has argued that the instant claims are distinguishable over the cited art Parsons since Parsons does not teach an absorbent member that extends through the shaped area of the channel. The Examiner disagrees. Applicant has claimed an absorbent material couple to the outlet of a channel. The Examiner believes that this is what is provided in the reference. Parsons shows an absorbent member (4) at the end of the entry channel which is used to draw a fluid through the channel. The Examiner also contends that extending the absorbent member into the channel of Parsons would provide the shape claimed by applicant. This extension would be obvious to one of ordinary skill in the art. One of ordinary skill in the art would recognize that the absorbent member could be placed anywhere within the channel to draw fluid through it. This would provide an absorbent member in which the member itself and its shape is used to control the fluid flow. Therefore, the claims remain rejected.

In reference to claim 6, applicant has argued that gravitational flow distinguishes the amended claim over the references. The Examiner contends this would be an intended use of the device. That is, for gravitational flow to even be a consideration, the device would have to be used in a manner which encourages a downward flow. As this has not been cited in the claim, the Examiner fails to see how simply flowing material in the channel would provide an additional component of flow control which is not already provided in the cited references.

In reference to claims 7 and 8, applicant has argued that the instant claim is distinguished over since the references do not contain a "template" but merely a number of viewing ports. The Examiner fails to see how a "template" is distinguishable over a number of viewing ports. Applicant has placed no structural limitations on the template but merely claims that this template may be used to determine the concentration within said channel. This is also what the references cited by the Examiner state is possible with their viewing port. The Examiner fails to see how one is distinguishable over the other since both may be used to sufficiently determine concentration within the stream. If applicant wishes to distinguish the "template" of viewing element over the ports cited by the Examiner, some structural elements which are different than the references would be required at the very least.

Finally, in reference to claim 9, applicant has claimed that recited coupling section is distinguishable over the prior art's coupling section. Applicant appears to be arguing beyond the scope of the claim here. Applicant is arguing that the structure eliminates air bubbles, but this feature is not sufficiently claimed. Applicant has merely recited a limitation of a "coupling

region sized such that fluid entering the region from either of said first or second channel outlet openings enters said main microfluidic channel without blocking said outlet opening of the other said channel." The Examiner contends that any coupling region which allows the joining of two entry channels while still allowing the contents of these two channels to flow down the main channel meets this limitation. The reference Yager appears to meet this limitation since fluids enter a main channel from two entry channels.

Conclusion

12. As previously stated by the Examiner, new grounds of rejection were applied due to a previous oversight involving claim 16. For this reason, this action was not made Final.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (703)-305-0211. The examiner can normally be reached on Monday-Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703)-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703)-772-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0661.

Jill Warden
Supervisory Patent Examiner
Technology Center 1700

dkh

October 21, 2002